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Tonix Pharmaceuticals Holding Corp. (TNXP-NASDAQ)

TNXP: Topline Results from Phase 3 RESILIENT Study in Fibromyalgia Expected in Late December 2023…

Based on our probability adjusted DCF model that takes into account potential future revenues from the company's CNS, immunology, and biodefense programs, TNXP is valued at $3.00/share. This model is highly dependent upon continued clinical success of the company's assets and will be adjusted accordingly based upon future clinical results.

Current Price (12/04/23)	$0.53
Valuation	**$3.00**

OUTLOOK

On November 9, 2023, Tonix Pharmaceuticals Holding Corp. (TNXP) announced financial results for the third quarter of 2023 and provided a business update. We anticipate topline results from the Phase 3 RESILIENT trial of TNX-102 SL in fibromyalgia in late December 2023. If successful, it would be the final efficacy trial required to submit a New Drug Application (NDA) for TNX-102 SL in the treatment of fibromyalgia. We also expect topline results from the Phase 2 proof-of-concept study of TNX-1900 in chronic migraine in early December 2023. The company continues its transition to obtaining external support for clinical trials from U.S. government agencies and other institutions, including four Phase 2 investigator-initiated studies of TNX-1900 for the treatment of adolescent obesity, binge eating disorder, social anxiety, and autism spectrum disorder.

SUMMARY DATA

52-Week High	**$8.13**
52-Week Low	**$0.46**
One-Year Return (%)	**-78.60**
Beta	**2.44**
Average Daily Volume (sh)	**289,175**
Shares Outstanding (mil)	**24**
Market Capitalization ($mil)	**$12**
Short Interest Ratio (days)	**N/A**
Institutional Ownership (%)	**6**
Insider Ownership (%)	**2**
Annual Cash Dividend	**$0.00**
Dividend Yield (%)	**0.00**
5-Yr. Historical Growth Rates	
Sales (%)	**N/A**
Earnings Per Share (%)	**N/A**
Dividend (%)	**N/A**
P/E using TTM EPS	**N/A**
P/E using 2023 Estimate	**-0.1**
P/E using 2024 Estimate	**-0.1**

Risk Level	**Above Avg.**
Type of Stock	**Small-Value**
Industry	**Med-Drugs**

ZACKS ESTIMATES

Revenue
(In millions of $)

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2022	0 A	0 A	0 A	0 A	0 A
2023	0 A	0 A	4 A	4 E	8 E
2024					18 E
2025					19 E

Earnings per Share

	Q1 (Mar)	Q2 (Jun)	Q3 (Sep)	Q4 (Dec)	Year (Dec)
2022	-$10.12 A	-$7.64 A	-$4.32 A	-$3.42 A	-$20.44 A
2023	-$3.26 A	-$2.68 A	-$1.83 A	-$1.64 E	-$8.80 E
2024					-$2.69 E
2025					-$1.91 E

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Business Update

Topline Results for Phase 3 RESILIENT Study Expected Late December 2023

On November 15, 2023, Tonix Pharmaceuticals Holding Corp. (TNXP) announced the completion of the clinical phase of the Phase 3 RESILIENT trial of TNX-102 SL 5.6 mg for the management of fibromyalgia. The double blind, placebo controlled study enrolled 457 patients and we anticipate topline results in late December 2023. If the study is successful, we expect it to be the final trial required for submission of a New Drug Application (NDA) for approval by the U.S. FDA.

The company disclosed that the unaudited rate of adverse event (AE)-related discontinuations in the RESILIENT study was 4.8%. This is in comparison to the AE-related discontinuation rates in the RELIEF study (6.0%) and the RALLY study (10.7%). The RELIEF study achieved statistical significance on the primary endpoint (*P*=0.010) while the RALLY study was stopped at the interim analysis. With the AE-related discontinuation rate for the RESILIENT study closer to the rate in the RELIEF study than the RALLY study, we believe this may be a positive sign, as AE-related discontinuations are treated as negative outcomes in the 'missing data' multiple imputation statistical analysis that is part of the analysis of the primary endpoint.

Since 2010, the FDA has generally required that 'missing data' be accounted for using a statistical method, and a commonly applied one is called "multiple imputation" (MI). The following table shows what the results for the RALLY and RELIEF study were using both mixed model repeated measures (MMRM)+MI and just MMRM. The data show that without MI, the results for the RALLY study are comparable to the positive results from the RELIEF study. The effect of the high discontinuation rate in the RALLY study and the MI treatment of the missing data is evidenced by the negative statistical outcomes. We are hopeful that without a large amount of missing data in the RELIEF study (4.8% discontinuation rate) the results will mirror those of the RELIEF study as opposed to the RALLY study.

	RALLY (F306)			
	MMRM+MI*		MMRM**	
Endpoints	LSMD (SE)	*p*-value	LSMD (SE)	*p*-value
Pain by Diary#	-0.2 (0.16)	**0.115**	-0.4 (0.16)	0.014
FIQR Symptom domain	-1.9 (1.52)	0.216	-3.4 (1.55)	0.030
FIQR Function domain	-0.4 (1.46)	0.797	-1.6 (1.48)	0.266
PROMIS Sleep Disturbance	-2.3 (0.80)	0.004	-3.3 (0.73)	<0.001
PROMIS Fatigue	-1.2 (0.74)	0.101	-2.0 (0.73)	0.007
Sleep Quality by Diary	-0.3 (0.16)	0.094	-0.4 (0.16)	0.008
	RELIEF (F304)			
	MMRM+MI*		MMRM**	
Endpoints	LSMD (SE)	*p*-value	LSMD (SE)	*p*-value
Pain by Diary#	-0.4 (0.16)	**0.010**	-0.5 (0.16)	0.004
FIQR Symptom domain	-4.3 (1.60)	0.007	-5.6 (1.60)	<0.001
FIQR Function domain	-4.4 (1.69)	0.009	-5.2 (1.63)	0.001
PROMIS Sleep Disturbance	-2.9 (0.82)	<0.001	-3.3 (0.82)	<0.001
PROMIS Fatigue	-1.8 (0.76)	0.018	-2.1 (0.79)	0.007
Sleep Quality by Diary	-0.6 (0.17)	<0.001	-0.7 (0.17)	<0.001

FIQR = Fibromyalgia Impact Questionnaire-Revised; LSMD = least squares mean difference (between TNX-102 SL and placebo); MMRM = mixed model repeated measures; MI = multiple imputation; PROMIS = Patient-Reported Outcomes Measurement Information System; SE = standard error

* MMRM with MI was the pre-specified primary analysis

**MMRM without MI was a pre-specified analysis

Primary efficacy endpoint: change from baseline in the weekly average of daily diary pain severity numerical rating scale scores

TONIX PHARMACEUTICALS

Source: Tonix Pharmaceuticals Holding Corp.

Topline Results for Phase 2 PREVENTION Study of TNX-1900 in Chronic Migraine Expected Early December 2023

In early December 2023, we anticipate topline results from the Phase 2 PREVENTION study of potentiated intranasal oxytocin (TNX-1900) for the prevention of migraine headaches in chronic migraineurs. It is a double blind, randomized, multicenter, placebo controlled study with three arms: two treatment regimens of TNX-1900 and one of placebo in a 1:1:1 ratio. After a four-week run-in phase to confirm chronic migraine criteria are met, the participants were treated for 12 weeks followed by a two-week safety follow up. The primary efficacy endpoint is the mean change in the number of migraine headache days between the 28-day run-in phase and the last 28-days of the treatment phase. The threshold for achieving proof-of-concept is an effect size > 0.2.

Outside Funding Becoming a Focus

Tonix has begun focusing on attaining funding from external sources for clinical trials in an effort to keep costs under control. Examples of this include:

- The U.S. National Institutes of Health (NIH) and National Institute of Allergy and Infectious Diseases (NIAID), through Project NextGen, will conduct a Phase 1 study of TNX-1800. That study is expected to initiate in the second half of 2024. See below for additional details.

- The National Institute of Drug Abuse (NIDA) is supporting the Phase 2 study of TNX-1300 for cocaine intoxication. The study is expected to start enrolling patients in the fourth quarter of 2023.

- The U.S. Department of Defense (DoD) is supporting the upcoming Phase 2 study of TNX-102 SL in acute stress disorder, which is being conducted and sponsored by the University of North Carolina. The $3 million grant is expected to support a trial that will enroll approximately 180 trauma survivors at study sites around the U.S. Enrollment is expected to initiate in the beginning of 2024.

- Massachusetts General Hospital is conducting Phase 2 studies of TNX-1900 in binge eating disorder, pediatric obesity, and bone health in children with autism spectrum disorder (AUD).

- The University of Washington is conducting a Phase 2 study of TNX-1900 in social anxiety disorder.

TNX-1800 Selected by NIH Project NextGen

On November 2, 2023, Tonix announced that the NIAID, a part of the NIH, will be conducting a Phase 1 clinical trial with TNX-1800, a live, replicating viral vaccine that expresses the SARS-CoV-2 spike protein. We anticipate the trial initiating in the second half of 2024. TNX-1800 is based on the company's horsepox vector platform. Orthopoxviruses are known to induce strong innate and adaptive immune responses along with long-lasting T cell immunity.

Tonix previously announced positive efficacy for TNX-1800 in non-human primates. The study was designed to compare TNX-1800 (modified horsepox virus encoding SARS-CoV-2 spike protein) to TNX-801 (horsepox virus) at two different doses with a control group receiving placebo. Four animals were included for each of the five groups.

Forty-one days following vaccination (or placebo), each animal was administered SARS-CoV-2 by intra-tracheal (1×10^6 $TCID_{50}$) and intra-nasal (1×10^6 $TCID_{50}$) administration. $TCID_{50}$ is a method for quantifying virus particles and represents a dilution that causes 50% of cells to display cytopathic effects. Six days after viral challenge, upper airway virus was examined through oropharyngeal swab and lower airway virus by tracheal lavage using qRT-PCR to quantitate the number of genome copies of SARS-CoV-2 present. The results showed that no samples (0/8) from animals vaccinated with TNX-1800 showed infection (defined as > 1,000 genome copies of SARS-CoV-2) in either the upper or lower airways. All animals vaccinated with TNX-801 (8/8) as a negative control or placebo (4/4) showed infection in either the upper or lower airways. These data are particularly important as they differentiate TNX-1800 from the current mRNA COVID vaccines in the ability to provide sterilizing immunity in non-human primates, and presumably will elicit the same type of response in humans.

The company also disclosed that on Day 14 after vaccination, all (8/8) TNX-1800-vaccinated animals had anti-CoV-2 neutralizing antibodies (≥1:40 titer) while none of the TNX-801 (0/8) or placebo-vaccinated (0/4) developed anti-CoV-2 neutralizing antibodies (≤1:10 titer). Six days after challenge with SARS-CoV-2, TNX-1800-vaccinated animals showed neutralizing antibody titers (≥1:1280 titer), which was similar between the low and high dose TNX-1800 groups (1×10^6 PFU and 3×10^6 PFU, respectively). In addition, all vaccinated animals developed a 'take',

which is a small lesion at the site of the immunization of a live, replicating virus vaccine that occurs approximately one week following dosing. The 'take' is a surrogate biomarker of a strong T cell immune response and is important as it is costly to measure the T cell response to a vaccine through *in vitro* studies. Thus, TNX-1800 elicits a complete immune response that stimulates the production of specific B cells, neutralizing antibodies, and T cells.

Financial Update

On November 9, 2023, Tonix announced financial results for the third quarter of 2023. The company reported net sales of $4.0 million for the three months ending September 30, 2023, compared to $0 in the third quarter of 2022. The net sales in the current quarter were the result of the Upsher Smith acquisition in which Tonix acquired Zembrace Symtouch and Tosymra. Net sales of Zembrace totaled $3.3 million during the current quarter while net sales of Tosymra totaled $0.7 million.

R&D expenses for the third quarter of 2023 were $21.1 million, compared to $22.2 million for the third quarter of 2022. The decrease was primarily due to decreased non-clinical and manufacturing expenses partially offset by an increase in clinical, employee-related, and professional expenses. G&A expenses for the third quarter of 2023 were $8.7 million, compared to $7.4 million for the third quarter of 2022. The increase was primarily due to sales and marketing associated with the recently acquired marketed products.

Net loss available to common shareholders for the third quarter of 2023 was $28.0 million, or $1.83 per share, compared to a net loss available to common shareholders of $29.0 million, or $4.24 per share for the third quarter of 2022. The weighted average common shares outstanding for the third quarter of 2023 were approximately 15.3 million compared to approximately 6.8 million in the third quarter of 2022.

As of September 30, 2023, Tonix had approximately $6.9 million in cash and cash equivalents. Subsequent to the end of the quarter, Tonix raised gross proceeds of $4.5 million from a public offering of common stock. As of November 9, 2023, Tonix had approximately 23.8 million shares outstanding and, when factoring in stock options and warrants, a fully diluted share count of approximately 55.2 million.

Conclusion

We are looking forward to the two clinical readouts expected in December 2023: results from the Phase 2 PREVENTION study of TNX-1900 in chronic migraine are expected early in the month while results from the Phase 3 RESILIENT study of TNX-102 SL in fibromyalgia are expected later in the month. Positive results from the Phase 3 trial in fibromyalgia could potentially lead to an NDA filing in 2024. We have adjusted our model based on the recent financing and our valuation is now $3.00 per share.

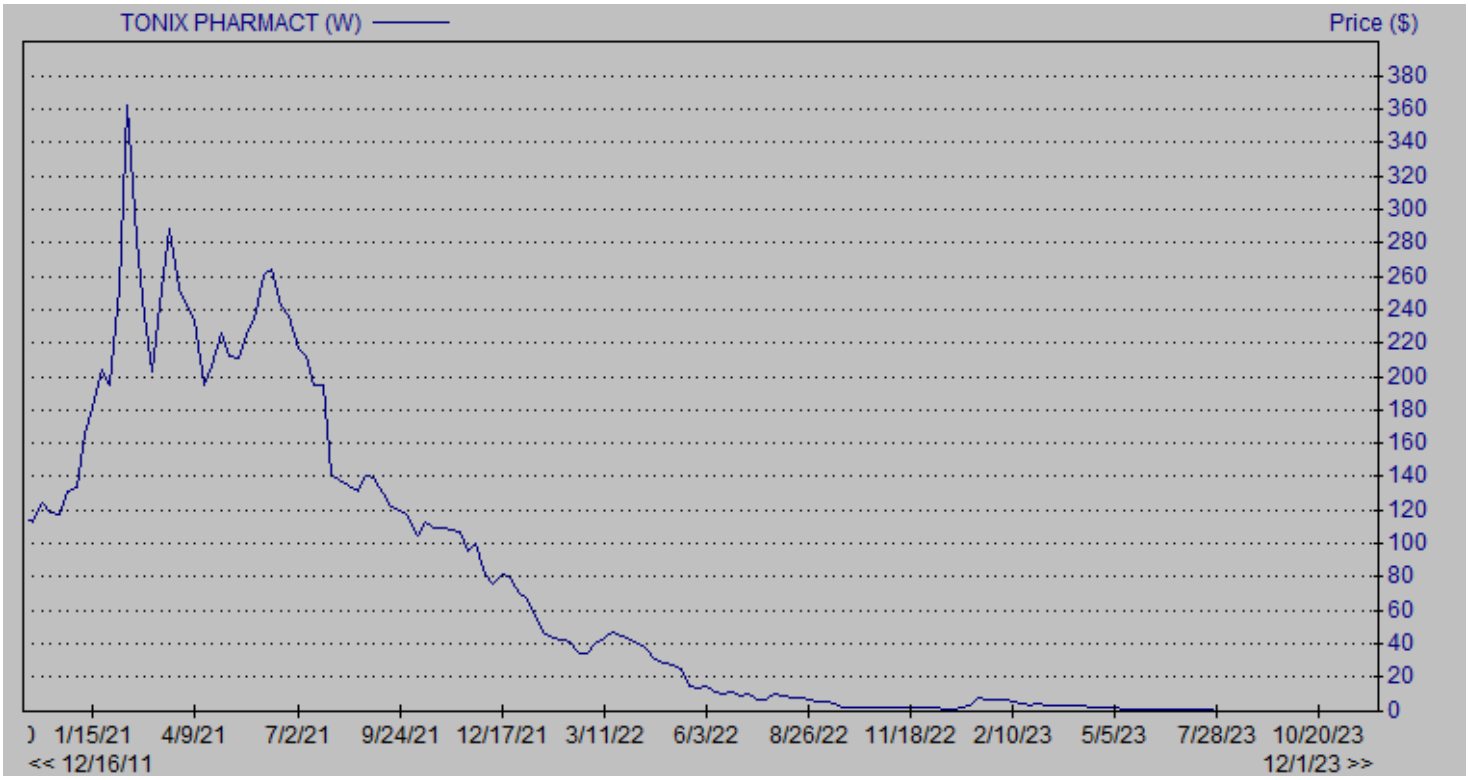
PROJECTED FINANCIALS

Tonix Pharmaceuticals	2022 A	Q1 A	Q2 A	Q3 A	Q4 E	2023 E	2024 E	2025 E
TNX-102 SL (FM)	$0	$0	$0	$0	$0	$0	$0	$0
Zembrace / Tosymra	$0	$0	$0	$4	$4	$8	$18	$19
Research & Collaborations	$0	$0	$0	$0	$0	$0	$0	$0
Total Revenues	**$0**	**$0**	**$0**	**$4**	**$4**	**$8**	**$18**	**$19**
CoGS	$0.0	$0	$0	$2	$2	$4.8	$10.7	$11.4
Product Gross Margin	-	-	-	*40.5%*	*40.0%*	*40.2%*	*40.6%*	*40.0%*
R&D	$81.9	$26.5	$22.0	$21.1	$22.0	$91.5	$55.0	$50.0
SG&A	$30.2	$7.4	$7.0	$8.7	$10.0	$33.1	$35.0	$36.0
Operating Income	($112.1)	($33.9)	($29.0)	($28.1)	($30.4)	($121.5)	($82.7)	($78.4)
Operating Margin	-	-	-	-	-	-	-	-
Interest & Other Income	$1.9	$0.9	$0.6	$0.2	$0.8	$2.5	$2.0	$2.0
Pre-Tax Income	($110.2)	($33.0)	($28.4)	($28.0)	($29.6)	($118.9)	($80.7)	($76.4)
Preferred Stock Deemed Dividend	$6.7	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0
Warrant Deemed Dividend	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0
Taxes & Other	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0	$0.0
Tax Rate	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*	*0%*
Net Income	($116.9)	($33.0)	($28.4)	($28.0)	($29.6)	($118.9)	($80.7)	($76.4)
Net Margin	-	-	-	-	-	-	-	-
Reported EPS	**($20.44)**	**($3.26)**	**($2.68)**	**($1.83)**	**($1.64)**	**($8.80)**	**($2.69)**	**($1.91)**
YOY Growth	*56.7%*	-	-	-	-	*-82.8%*	*-94.8%*	*-81.1%*
Weighted Shares Outstanding	5.7	10.1	10.6	15.3	18.0	13.5	30.0	40.0

Source: Zacks Investment Research, Inc. *David Bautz, PhD*

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